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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/546,201	04/10/2000	John M. Polo	930049.464/1463.002	3605

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Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/04/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/546,201

Applicant(s)

POLO ET AL.

Examiner

Shanon A. Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,28-31 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,28-31 and 33-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant has cancelled claims 1-25, 27, 32, and 45 and amended claims 26, 28, 30, 31, 34, and 44. Claims under consideration are 26, 28-31, and 33-44. Applicant has argued convincingly regarding previous rejections. However, upon reconsideration, new grounds of rejection are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28-31, and 33-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On aspect of claim 26 is drawn to encoding a viral agent from a pathogenic agent. Claim 28 states that the antigen is a viral antigen and claim 30 states that the pathogenic agent is a bacteria, parasite, or fungus. Does this mean that the viral antigen is derived from only viruses that infect bacteria, parasites, or fungus? However, this is clearly not what applicant intends because claim 29 lists viruses that infect humans and felines, and not any of the other pathogenic agents listed in claim 30. This rejection is merely to bring this inconsistency to applicant's attention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 28-31, and 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubensky et al. (US 6,015,686), Polo et al. (Nature Biotechnology. 1998; 16: 517-518), and Cella et al. (J. Exp. Med. 1999; 189 (5): 821-829.).

The claims are drawn to an expression cassette that has two promoters. The first is operably linked to a nucleic acid (na) that forms a dsRNA molecule in vivo that induces the production of interferon the second promoter (RNA pol II) that is operably linked a NA that encodes a viral antigen from a pathogenic agent. The pathogenic agent is a bacteria, tumor, parasite, or fungus. The expression cassette is any virus that is conventionally used as gene delivery vehicles and is a eukaryotic layered gene delivery initiation system and a cell comprising the expression cassette.

Dubensky et al. (6,015,686) teaches a eukaryotic layered vector initiation cassette that expresses a heterologous sequence from RSV, HPV, HBV, HCV, EBV, HIV, HSV, FeLV, FIV, Hantavirus, HTLV I, HTLV II, and CMV, under the control of an RNA polymerase II promoters see claim 9 and column 4, lines 36-46, and column 114, lines 30-37. Dubensky et al. also teaches that the vector can utilize any of the promoters listed in claim 33, see column 4, lines 8-12. In addition, the vector can also direct the expression of bacterial, fungal, and parasitic antigens, see column 28, lines 4-19, and/or be anti-cancer related, see column 27, line 60 to column 28, line 2. The reference also teaches that a wide variety of vectors can be utilized as the first layer of the vector initiation system, such as retrovirus, herpesvirus, and poxvirus, see column 32, lines 26-68, and further teach that the system is expressed in a cell line, see claims 12-15 and 20.

Dubensky et al. does not teach expressing dsRNA in the vector system. However, Dubensky et al. does teach that more than one heterologous sequence is expressed in the vector system, see column 28, lines 4-19, and is not limited to antigens from pathogens, but also includes other forms of nucleotides, such as those encoding non-coding sequences, see claim 10. One of ordinary skill in the art would have been motivated to incorporate a sequence that encodes dsRNA because Cella et al. (J Exp. Med. March 1, 1999; 189 (5): 821-829) teach dendritic cells activated by dsRNA increases antigen presentation and activate naïve T cells and stimulate T helper responses. Polo et al. (Nature Biotechnology. June 1998; 16 (6): 517-518) teach that alphavirus vector RNA molecules replicate through dsRNA intermediates that are able to induce production of interferons, see the first and second columns on page 518.

One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate dsRNA into the expression cassette taught by Dubensky et al. to increase viral antigen presentation taught by Cella et al. and induce interferon production, taught by Polo et al.. One would be further motivated to induce expression of the dsRNA with a different promoter from the RNA polymerase II promoter that expresses the antigen because one would want to be able to separately control the amount of expression of the antigen and the dsRNA. Polo et al. also teaches theoretical concerns that a specific immune response could be triggered against the alphavirus replicase proteins, see the second paragraph of the third column. Therefore, the skilled artisan would only be motivated to express alphavirus genes under the control of a heterologous promoter that is capable of producing dsRNA without the risk of specific immune response in the host against the alphavirus. One of ordinary skill in the art would have had a reasonable expectation in producing the claimed invention because Dubensky

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et al. teach that the eukaryotic layered gene delivery initiation system is used to express more than one antigen with different promoters and lists all of the optional promoters, which are also present in the instant claims. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SAF
Shanon Foley/SAF
November 1, 2001

James C. Housel 12/3/01
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600